EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	C.A. No. 22-252 (MSG) **HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY**
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	

DEFENDANTS' FIFTH SUPPLEMENTAL OBJECTIONS AND RESPONSES TO PLAINTIFFS' FIRST SET OF INTERROGATORIES (NOS. 1–10)

Pursuant to Fed. R. Civ. P. 33, Defendants Moderna, Inc. and ModernaTX Inc. (collectively, "Moderna" or "Defendants") provide their Third Supplemental Objections and Responses to Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH's ("Genevant," collectively "Plaintiffs") First Set of Interrogatories (Nos. 1–10).

SPECIFIC OBJECTIONS AND RESPONSES

INTERROGATORY NO. 1:

Do you admit that the manufacture, use, sale, offer for sale, and/or importation of the Accused Product would infringe, either literally or under the doctrine of equivalents, any of the asserted claims of the Patents-in-Suit, assuming the asserted claims to be valid and enforceable? If your answer is anything other than an unqualified "Yes," then for each claim for which your answer is anything other than an unqualified "Yes," state all bases on which you contend the asserted claim would not be infringed either literally or under the doctrine of equivalents, including any basis upon which you assert that Plaintiffs are estopped from asserting infringement by the doctrine of equivalents.

RESPONSE TO INTERROGATORY NO. 1:

Moderna objects to this Interrogatory as premature and unanswerable at this time because Plaintiffs have not yet served Infringement Contentions or identified Asserted Claims of the Patents-in-Suit. Moderna objects to this Interrogatory as premature and unanswerable at this time because Plaintiffs have not identified any theories under the doctrine of equivalents. Moderna objects to this Interrogatory on the ground that it seeks premature discovery in advance of the dates to be set out by the Court or agreed to by the parties because it seeks to elicit a claim construction position. Moderna objects to this Interrogatory to the extent it seeks to improperly shift the burden of proving infringement. Moderna objects to this Interrogatory to the extent it seeks information protected from discovery by the attorney-client privilege, attorney work product doctrine, or any other applicable privilege or immunity, and Moderna will not provide or produce such information. Moderna objects to this Interrogatory as premature to the extent that it calls for the rendering of an expert opinion.

Subject to the General and Specific Objections, Moderna responds as follows:

Because Plaintiffs have not yet identified the Asserted Claims of the Patents-in-Suit nor any theories of alleged infringement, including under the doctrine of equivalents, Moderna is unable to answer this Interrogatory completely. Regardless, Moderna does not admit that the

manufacture, use, sale, offer for sale, and/or importation of Moderna's COVID-19 Vaccine would infringe, either literally or under the doctrine of equivalents, any claim of the Patents-in-Suit. *See, e.g.*, D.I. 35.

Plaintiffs bear the burden of proving that the Accused Products infringe the Asserted Claims. Plaintiffs have not met that burden. Indeed, Plaintiffs have not yet served infringement contentions. Moderna does not concede that Plaintiffs have proven direct or indirect literal infringement or infringement under the doctrine of equivalents of any element of the Asserted Claims, and Moderna reserves the right to challenge the sufficiency of proof of infringement of any and all elements of the Asserted Claims.

A. No Direct or Indirect Infringement: The Asserted Claims are Invalid

The Accused Products do not directly or indirectly infringe any of the Asserted Claims because an invalid claim cannot be infringed. *Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("The claim being invalid there is nothing to be infringed."); *Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 412 F.3d 1284, 1291 (Fed. Cir. 2005) ("there can be no ... induced infringement of invalid patent claims"). Moderna incorporates by reference its forthcoming Invalidity Contentions to be served according to the scheduling order and any amendments or supplementations thereto that each Asserted Claim is invalid under, *inter alia*, 35 U.S.C. §§ 102–103, 112. Because the Asserted Claims are invalid, the Accused Products cannot infringe.

B. No Direct or Indirect Infringement: 35 U.S.C. § 271(e)(1)

Moderna's development activities relating to the Accused Products do not directly or indirectly infringe any of the Asserted Claims because they are protected under the safe harbor provision of 35 U.S.C. § 271(e)(1), which reads, in relevant part:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses *reasonably related* to the

> development and submission of information under a Federal law which regulates the *manufacture, use, or sale of drugs* . . . .

The Supreme Court has construed the safe harbor provision broadly, holding that the exemption "extends to all uses of patented invention that are reasonably related to the development and submission of *any* information under the FDCA" (original emphasis), and that the "reasonably related" requirement will be met "[a]t least where a drugmaker has a reasonable basis for believing that a patented compound *may* work … and uses the compound in research that, *if successful*, would be appropriate to include in a submission to the FDA" (emphasis added). *Merck KGaA v. Integra Lifesciences I, Ltd*., 545 U.S. 193, 202 (2005). Consistent with the broad construction, the safe harbor provision protects uses of patented compounds in both clinical studies and preclinical studies and research, whether or not the experiments are ultimately submitted to the FDA. *Id*.

The Federal Circuit similarly held that the safe harbor applies "as long as there is a reasonable basis for believing that the use of the patented invention will produce the type of information that are relevant to an FDA submission." *Amgen v. Hospira*, 944 F.3d 1327, 1338 (Fed. Cir. 2019); *see also, e.g.*, *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1360 (Fed. Cir. 2012) ("As long as the use of the patented invention is done to generate information that will be submitted pursuant to a relevant federal law, that use falls within the safe harbor."); *Classen Immunotherapies, Inc. v. Elan Pharmaceuticals, Inc.*, 786 F.3d 892, 897-99, 115 U.S.P.Q.2d (Fed. Cir. 2015) (instructing that in some limited circumstances post-approval testing can be subject to the safe harbor of Section 271(e), and finding that accused infringer's post-approval clinical trials and additional FDA submissions were subject to the safe harbor provision since they were necessary to obtain continued approval of the generic drug).

Moderna's development, preclinical, and clinical activities relating to FDA Emergency Use Authorization and approval of the Accused Products are exempted from infringement under

Section 271(e)(1). For example, Moderna has made submissions to the FDA in the following applications to the FDA relating to the Accused Products:

- IND 19745
- EUA 27073
- BLA 125752

The manufacture and use of batches of the Accused Products relevant to submissions in the above FDA applications are exempted from infringement under Section 271(e)(1). Moderna's investigation with respect to this issue is ongoing.

C. 28 U.S.C. § 1498

Moderna incorporates by reference its briefing on its Partial Motion to Dismiss, which establishes that the Government accepted liability under 28 U.S.C. § 1498 for doses procured under Contract No. W911QY-20-C-0100 (the "'-0100 Contract") with the U.S. Government. *See, e.g.*, D.I. 17 at 8; D.I. 49 at 1, 4.

* * *

Moderna incorporates by reference its Counterclaims for Declaratory Judgment of Noninfringement for each of the Patents-in-Suit.

Moderna's investigation is ongoing and Moderna reserves the right to supplement, revise, or amend Moderna's Response to this Interrogatory as discovery and Moderna's investigation in this Action proceed.

FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 1 (June 12, 2023):

Subject to the General and Specific Objections, Moderna further responds as follows:

Moderna's ability to respond to this Interrogatory has been prejudiced by Plaintiffs' deficient infringement contentions, which Plaintiffs have not yet rectified. For example, Plaintiffs have failed to identify or to differentiate between the different formulations of Moderna's COVID-

19 Vaccine in their contentions. Plaintiffs' allegations of infringement under the doctrine of equivalents are conclusory at best, without any analysis as to function-way-result. *See, e.g.* Afinogenova May 12, 2023 letter.

Moderna repeats and incorporates by reference its initial response to this Interrogatory.

A. The '651 Patent Is Not Infringed

Moderna's COVID-19 Vaccine does not meet at least the following limitations:

- Plaintiffs have not provided infringement contentions detailing whether Moderna's COVID-19 Vaccine contains the recited percentages mRNA that is allegedly "***fully*** encapsulated." As a result, Moderna's COVID-19 Vaccine does not infringe any of the Asserted Claims.
- Plaintiffs have failed to show that "***each*** lipid vesicle is about 150 nm or less in diameter," or that "***each*** lipid vesicle is about 100 nm or less in diameter" as required by Claims 10 and 12. Instead, Plaintiffs cite references that at most describe average size. As a result, Moderna's COVID-19 Vaccine does not infringe these claims.
- Plaintiffs have not adequately explained their infringement contentions for "wherein each lipid vesicle is a liposome" (claim 8) and "wherein each lipid vesicle is a lipid-nucleic acid particle" (claim 9). *See, e.g.* Afinogenova May 12, 2023 letter. As a result, Moderna's COVID-19 Vaccine does not infringe these claims.

B. The '069, '359, '668, '435, and '378 Patents Are Not Infringed

1. No Direct or Indirect Infringement of Asserted Claims of the '069, '359, '668, '435, and '378 Patents: [redacted]

[redacted]

[redacted] Moderna incorporates by reference its response to Interrogatory No. 7.

[redacted]

[redacted]

The [redacted] does not infringe the referenced claims under the doctrine of equivalents, applying either the function-way-result test, or the insubstantial differences test. If Plaintiffs provide adequate infringement contentions for these claim elements under the doctrine of equivalents, Moderna reserves the right to supplement this response to address those arguments.

In addition, prosecution history estoppel precludes any potential argument by Plaintiffs that [redacted]. For example, claim amendments and arguments made during prosecution of a patent application can create an estoppel, thereby preventing the patent owner from recapturing subject matter through the doctrine of equivalents that was surrendered during prosecution of the patent. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 722, 736 (2002) ("[A] narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an estoppel"). Further, when an amendment is made to narrow claims in a parent application, the estoppel that is associated with the parent application applies to any continuation application that uses the same claim term. *Biovail Corp. Intern. v. Andrx Pharmaceuticals, Inc.*,

239 F.3d 1297, 1304, 57 U.S.P.Q.2d 1813 (Fed. Cir. 2001) (affirming bench verdict of no infringement under doctrine of equivalents where patentee added claim amendment in a grandparent application to overcome prior art and therefore prosecution history estoppel applied to the same term as used in claims issuing from a later continuation application to bar doctrine of equivalents) (post-*Festo*).

The prosecution history of the '069 patent clearly establishes that the applicants surrendered claim scope to overcome the examiner's patentability rejection, which precludes the application of doctrine of equivalents. For example, during the '069 patent prosecution, the applicants deleted "about" from the then-pending claims to narrow the ranges of lipid components in response to the examiner's Section 102 and 103 rejections:

> 1. (Currently amended) A nucleic acid-lipid particle comprising:
> (a) a nucleic acid;
> (b) a cationic lipid comprising from ~~about~~ 50 mol % to ~~about~~ 65 mol % of the total lipid present in the particle;
> (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from ~~about~~ 4 mol % to ~~about~~ 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from ~~about~~ 30 mol % to ~~about~~ 40 mol % of the total lipid present in the particle; and
> (d) a conjugated lipid that inhibits aggregation of particles comprising from ~~about~~ 0.5 mol % to ~~about~~ 2 mol % of the total lipid present in the particle.

'069 patent file history, Amdt. dated August 11, 2011 at 2. Specifically, the applicants stated:

> During the interview, Applicants' representatives proposed amending the claims to delete the word 'about' form the ranges of lipid components and argued that the claimed ranges were not anticipated by McLachlan *et al*. … because that reference failed to disclose the claimed ranges with sufficient specificity …

* * *

> In making both rejections, ***the Examiner alleges that the term 'comprising from about' recited in the instant embraces a broad range of lipid components.*** In an earnest effort to expedite prosecution, but without acquiescing on the merits of the rejection, ***Applicants have amended the claims to delete 'about' from the ranges of lipid components recited therein***.

Id. at 6–7 (emphasis added). Therefore, Plaintiffs are precluded from recapturing a nucleic acid-lipid particle comprising [redacted] under the doctrine of equivalents based on arguments and amendments during prosecution to overcome prior art rejections.

Similarly, Plaintiffs are estopped from asserting doctrine of equivalents to capture [redacted] for the '359, '668, '435, and '378 patents. During prosecution of the '359, '668, and '435 patents, for example, the applicants filed preliminary amendments to delete "about" from original claims reciting "a conjugated lipid . . . comprising from *about* 0.5 mol % to *about* 2 mol % of the total lipid." *See*, *e.g.*, '359 patent file history, Claims dated October 5, 2011 at 114, Amdt. dated March 28, 2012 at 4; '668 patent file history, Claims dated June 26, 2013 at 114, Amdt. dated November 6, 2013 at 5; '435 patent file history, Claims dated August 18, 2014 at 114, Amdt. dated February 26, 2015 at 2 (emphasis added). When pursuing the '378 patent, the applicants filed claims reciting a nucleic acid-lipid particle consisting essentially of a PEG-lipid conjugate ***consisting*** of "from 0.1 mol % to 2 mol % of the total lipid present in the particle," after narrowing its claims when prosecuting the '069, '359, '668, and '435 patents. *See, e.g.*, '378 patent file history, Claims dated April 12, 2021 at 121. Moreover, the disclosure in the specification demonstrates that applicants knew how to claim fractional percentages of the conjugated lipid when that was their intent. *E.g.*, '359 patent at 22:40–52 (listing ranges for the conjugated lipid including fractional percentages such as from about 1.2 mol % to about 1.7 mol %, from about 1.3 mol % to about 1.6 mol %, or about 1, 1.1,

1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, or 2 mol % (or any fraction thereof or range therein) of the total lipid present in the particle); 57:24–35.

Because the '359, '668, '435, and '378 patents are issued from continuation applications of the '069 patent and use claim terms identical to those in the '069 patent, Plaintiffs are estopped from arguing that Moderna's [redacted] infringes any Asserted Claims of the '359, '668, '435, and '378 patents requiring [redacted] under doctrine of equivalents. *Biovail Corp.*, 239 F.3d at 1304.

Plaintiffs are also estopped from recapturing [redacted] For example, during the IPR for the '069 patent, Plaintiffs alleged:

> The '069 patent is directed to the ***surprising discovery that nucleic acid-lipid particle formulations with high levels of cationic lipids and low levels of conjugated lipids*** exhibit favorable *in vivo* transfection efficiencies as well as "improved tolerability of the formulations in vivo, resulting in a significant increase in the therapeutic index [a measure of dosage relative to toxic effect] as compared to nucleic acid-lipid particle compositions previously described." . . . ***Reflecting this discovery, the '069 patent claims nucleic acid-lipid particle formulations with high levels of cationic lipids (50–65 mol %) and low levels of conjugated lipids (0.5–2 mol %)***—as well as specific levels of cholesterol/derivative (30-40 mol %) and phospholipid (4-10 mol %).

See, e.g., IPR2019-00554, Paper 7 (Patent Owner's Preliminary Response) at 13, 14, 45–46; *id.*, Paper 15 (Patent Owner's Response) at 7, 8, 29–30, 32, 62, 64.

During the IPR for the related '435 patent, Plaintiffs again alleged:

> The '435 patent discloses the ***"surprising discovery" that nucleic acid-lipid particle formulations with a high level of cationic lipid and a remarkably low level of conjugated lipid*** exhibited favorable *in vivo* transfection efficiencies as well as "improved tolerability of the formulations in vivo, resulting in a significant increase in the therapeutic index [a measure of dosage relative to toxic effect] as

> compared to nucleic acid-lipid particle compositions previously described." . . . ***Reflective of this discovery, the '435 patent claims nucleic acid-lipid particle formulations with a high level of cationic lipid (50–85 mol %) and an unconventionally low level of conjugated lipid (0.5–2 mol %)***.

See, e.g., IPR2018-00739, Paper 12 (Patent Owner's Preliminary Response) at 2, 6–8, 12, 24, 37; *id.*, Paper 24 (Patent Owner's Response) at 2, 14, 19–21, 32, 47, 59.

Plaintiffs further made statements during Appeal No. 20-1184 that made it clear that [redacted]

Thus, Plaintiffs are estopped from recapturing [redacted] under the '069 and '435 patents, as well as the '359, '668, and '378 patents, which are in the same family as the '069 and '435 patents and similarly claim [redacted]

Plaintiffs are further legally precluded from claiming that Moderna's [redacted] infringes any Asserted Claim of the '069, '359, '668, '435, and '378 patents under the doctrine of equivalents based on the doctrine of vitiation. The doctrine of equivalents cannot be used to vitiate meaningful limitations from the claims, as the public is entitled to rely on such limitations to avoid infringement. *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). Here, for example, vitiating the numerical limitations requiring [redacted] would deprive the public of the notice function of the claims, thus rendering the claims meaningless. *Mirror Worlds, LLC v. Apple Inc.*, 692 F.3d 1351, 1358 (Fed. Cir. 2012) ("an argument that the absence of a feature is equivalent to its presence" negates the doctrine of equivalents).

Plaintiffs are also legally precluded from claiming that Moderna's [redacted] infringes any Asserted Claims of the '069, '359, '668, '435, and '378 patents under the doctrine of equivalents based on the doctrine of public dedication because the specification of the patents discloses the unclaimed subject matter such that it has been dedicated to the public. *PSC Comput. Prods., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360, (Fed. Cir. 2004) ("The disclosure-dedication rule requires an inventor who discloses specific matter to claim it, and to submit the broader claim for examination. Otherwise, that matter is dedicated to the public and may not be recaptured under the doctrine of equivalents."). As an example, the specification of the '069 patent discloses embodiments that contain a conjugated lipid (*e.g.*, PEG-lipid conjugate) comprising "about 2 mol %" of the total lipid:

> In certain instances, the conjugated lipid that inhibits aggregation of particles (e.g., PEG-lipid conjugate) may comprise from about 0.1 mol % to about 2 mol %, from about 0.5 mol % to about 2 mol %, from about 1 mol % to about 2 mol %, from about 0.6 mol % to about 1.9 mol %, from about 0.7 mol % to about 1.8 mol %, from about 0.8 mol % to about 1.7 mol %, from about 1 mol % to about 1.8 mol %, from about 1.2 mol % to about 1.8 mol %, from about 1.2 mol % to about 1.7 mol %, from about 1.3 mol % to about 1.6 mol %, from about 1.4 mol % to about 1.5 mol %, or about 1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, or 2 mol % (or any fraction thereof or range therein) of the total lipid present in the particle.

See, e.g., '069 patent at 22:30–42, 68:39–48. The '069, '359, '668, '435, and '378 patents are in the same family and share the same specification. Because the '069, '359, '668, '435, and '378 patents claim a nucleic acid-lipid particle comprising a conjugated lipid consisting of "from 0.5 mol % to 2 mol %" or "from 0.1 mol % to 2 mol %" of the total lipid, while the specification discloses "from *about* 0.1 mol % to *about* 2 mol %" of a conjugated lipid (emphasis added), Plaintiffs are estopped from enforcing any unclaimed embodiments comprising [redacted]. *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1107 (Fed. Cir. 2000).

Plaintiffs is further legally precluded from claiming that Moderna's [redacted] infringes any Asserted Claims of the '069, '359, '668, '435, and '378 patents under the doctrine of equivalents because to do so would ensnare the prior art (*see, e.g.* the references in Exhibit B of Moderna's Invalidity Contentions). If the claims were to literally cover Moderna's [redacted] which contain [redacted], then the claims would encompass prior art. *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683 (Fed. Cir. 1990). Moderna incorporates by reference its Invalidity Contentions and any amendments or supplementations thereto concerning the '069, '359, '668, '435, and '378 patents.

2. No Direct or Indirect Infringement of Asserted Claims of the '069, '359, '668, '435, and '378 Patents: [redacted]

The [redacted] of the Accused Products comprising [redacted] do not infringe any Asserted Claims of the '069, '359, and '668 patents, which recite or incorporate a limitation requiring a nucleic acid-lipid particle comprising [redacted] and Asserted Claims of the '435 patent, which recite or incorporate a limitation requiring a nucleic acid-lipid particle comprising [redacted]

[redacted]

[redacted]

The [redacted] do not infringe the referenced claims under the doctrine of equivalents, applying either the function-way-result test, or the insubstantial differences test. If Plaintiffs provide adequate infringement contentions for these claim elements under the doctrine of equivalents, Moderna reserves the right to supplement this response to address those arguments.

In addition, prosecution history estoppel precludes any potential argument by Plaintiffs that Moderna's [redacted] infringe any Asserted Claims of the '069, '359, '668, and '435 patents requiring [redacted] under the doctrine of equivalents based on claim amendments and arguments during prosecution.

The prosecution history of the '069 patent clearly establishes that the applicants surrendered claim scope to overcome the examiner's patentability rejection, which precludes the application of doctrine of equivalents. For example, during prosecution of the '069 patent, the applicants deleted "about" from the then-pending claims to narrow the ranges of lipid components in response to the examiner's Section 102 and 103 rejections:

> 1. (Currently amended) A nucleic acid-lipid particle comprising:
>
> (a) a nucleic acid;
>
> (b) a cationic lipid comprising from ~~about~~ 50 mol % to ~~about~~ 65 mol % of the total lipid present in the particle;
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> (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from ~~about~~ 4 mol % to ~~about~~ 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from ~~about~~ 30 mol % to ~~about~~ 40 mol % of the total lipid present in the particle; and
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> (d) a conjugated lipid that inhibits aggregation of particles comprising from ~~about~~ 0.5 mol % to ~~about~~ 2 mol % of the total lipid present in the particle.

'069 patent file history, Amdt. dated August 11, 2011 at 2. Specifically, the applicants stated:

> During the interview, Applicants' representatives proposed amending the claims to delete the word 'about' form the ranges of lipid components and argued that the claimed ranges were not anticipated by McLachlan *et al*. … because that reference failed to disclose the claimed ranges with sufficient specificity ….
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> * * *
>
> In making both rejections, ***the Examiner alleges that the term 'comprising from about' recited in the instant embraces a broad range of lipid components.*** In an earnest effort to expedite prosecution, but without acquiescing on the merits of the rejection, ***Applicants have amended the claims to delete 'about' from the ranges of lipid components recited therein***.

Id. at 6–7 (emphasis added). Therefore, Plaintiffs are precluded from recapturing a nucleic acid-lipid particle comprising [redacted] under doctrine of equivalents, after the applicants relinquished such claim scope to overcome prior art during prosecution.

Further, to overcome the examiner's double patenting rejections, the applicants made arguments alleging unexpected results of the invention arising from [redacted]:

> In particular, Applicants reiterate that it is clear from the specification that the present invention is based, in part, on the surprising discovery that 1:57 SNALP formulations provide ***new and unexpected results*** when used for the *in vitro* or *in vivo* delivery of an active agent, such as a therapeutic nucleic acid *(e.g.,* an interfering RNA). In fact, Applicants have found that SNALP formulations having increased amounts of cationic lipid, *e.g.,* one or more cationic lipids comprising from 50 mol % to 65 mol % of the total lipid present in the particle, provide ***unexpectedly superior advantages*** when used for the *in vitro* or *in vivo* delivery of an active agent, such as a therapeutic nucleic acid *(e.g.,* an interfering RNA).
>
> * * *
>
> It is noted that the cited references disclose the preparation and testing of SN ALP formulations such as the 2:30, 2:40, and 10:15 SNALP formulations as exemplified formulations containing the greatest amount of cationic lipid *(i.e.,* 30 mol %, 40 mol %, and 15 mol % cationic lipid, respectively). As set forth in the instant specification and acknowledged by the Examiner, SNALP formulations having increased amounts of cationic lipid such as, *e.g.,* the 1 :57 SN ALP formulation, provide ***unexpectedly superior advantages*** over previously exemplified SNALP formulations containing lower amounts of cationic lipid.

Id. at 9–10 (original emphasis). The applicants' arguments, including those above, made during prosecution that characterize the alleged unexpected properties of the invention, attempt to distinguish the prior art, and purportedly identify critical attributes of the invention give rise to argument-based estoppel and limit the available equivalents.

Similarly, Plaintiffs are estopped from asserting the doctrine of equivalents to capture [redacted] for the '359, '668, and '435 patents. During prosecution of the '359 and '668 patents, the applicants filed preliminary amendments to delete "about" from original claims reciting "a cationic lipid comprising from *about* 50 mol % to *about* 65 mol % of the total lipid." *See, e.g.*, '359 patent file history, Claims dated October 5, 2011 at 114, Amdt. dated March 28, 2012 at 4; '668 patent file history, Claims dated June 26, 2013 at 114, Amdt. dated November 6, 2013 at 5 (emphasis added). Similarly, during prosecution of the '435 patent, the applicants filed preliminary amendments to delete "about" from original claims reciting "a cationic lipid

comprising from *about* 50 mol % to *about* 85 mol % of the total lipid." *See, e.g.*, '435 patent file history, Claims dated August 18, 2014 at 114, Amdt. dated February 26, 2015 at 2.

Because the '359, '668, and '435 patents are issued from continuation applications of the '069 patent and use claim terms identical to those in the '069 patent, Plaintiffs are estopped from arguing that Moderna's [redacted] infringe any Asserted Claims of the '359, '668, and '435 patents requiring [redacted] under doctrine of equivalents.

Plaintiffs are also estopped from recapturing [redacted] under the doctrine of equivalents because Plaintiffs repeatedly argued in IPR the alleged unexpected results and purported innovative aspects of the invention arising from [redacted] in an attempt to distinguish prior art. For example, during the IPR for the '069 patent, Plaintiffs alleged:

> The '069 patent is directed to the ***surprising discovery that nucleic acid-lipid particle formulations with high levels of cationic lipids and low levels of conjugated lipids*** exhibit favorable *in vivo* transfection efficiencies as well as "improved tolerability of the formulations in vivo, resulting in a significant increase in the therapeutic index [a measure of dosage relative to toxic effect] as compared to nucleic acid-lipid particle compositions previously described." . . . ***Reflecting this discovery, the '069 patent claims nucleic acid-lipid particle formulations with high levels of cationic lipids (50–65 mol %) and low levels of conjugated lipids (0.5–2 mol %)***—as well as specific levels of cholesterol/derivative (30-40 mol %) and phospholipid (4-10 mol %).

See, e.g., IPR2019-00554, Paper 7 (Patent Owner's Preliminary Response) at 13, 14, 34, 45–46 (emphasis added); *id.*, Paper 15 (Patent Owner's Response) at 7, 8, 29–30, 32, 62, 64.

During the IPR for the '435 patent, Plaintiffs again alleged:

> The '435 patent discloses the ***"surprising discovery" that nucleic acid-lipid particle formulations with a high level of cationic lipid and a remarkably low level of conjugated lipid*** exhibited favorable *in vivo* transfection efficiencies as well as "improved tolerability of the formulations in vivo, resulting in a significant increase in the therapeutic index [a measure of dosage relative to toxic effect] as

> compared to nucleic acid-lipid particle compositions previously described." . . . ***Reflective of this discovery, the '435 patent claims nucleic acid-lipid particle formulations with a high level of cationic lipid (50–85 mol %) and an unconventionally low level of conjugated lipid (0.5–2 mol %)***.

See, e.g., IPR2018-00739, Paper 12 (Patent Owner's Preliminary Response) at 2, 6–8, 12, 24, 26, 37 (emphasis added); *id.*, Paper 24 (Patent Owner's Response) at 2, 14, 19–21, 24, 32, 47, 54–55.

Thus, Plaintiffs are estopped from recapturing [redacted] under the '069 and '435 patents, as well as the '359 and '668 patents, which are in the same family as the '069 and '435 patents and similarly claim [redacted]

Similarly with respect to the '378 Patent, Plaintiffs attempted to broaden the scope of the claims by removing the limitation reciting [redacted] -- but in doing so, Plaintiffs failed to put the Examiner on notice that it was expressly rescinding the prior disclaimer and that the Examiner should re-examine the prior art in light of that broadening. *See, e.g., Hakim v Cannon Avent Grp*., 479 F.3d 1313 (Fed. Cir. 2007) ("[a]lthough a disclaimer made during prosecution can be rescinded, permitting recapture of the disclaimed scope, the prosecution history must be sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be re-visited."). Therefore, the disclaimer of [redacted] remains effective for the '378 Patent, and Moderna does not literally infringe any of the Asserted Claims of the '378 Patent. For the same reasons, Plaintiffs are legally precluded by prosecution history estoppel from recapturing [redacted]

Plaintiffs are further legally precluded from claiming that Moderna's [redacted] infringe any Asserted Claims of the '069, '359, '668, and '435 patents under the doctrine of equivalents based on the doctrine of vitiation. Here, for example, vitiating the numerical limitations requiring [redacted]% would deprive the public of the notice function of the claims, thus rendering the claims meaningless.

Plaintiffs are also legally precluded from claiming that Moderna's [redacted] infringe any Asserted Claims of the '069, '359, '668, and '435 patents under the doctrine of equivalents based on the doctrine of public dedication. Plaintiffs are precluded from asserting that any Asserted Claims of the '069, '359, '668, and '435 patents cover the [redacted] because the specification of the patents discloses the unclaimed subject matter such that it has been dedicated to the public. *PSC Comput. Prods.*, 355 F.3d at 1360. The '069, '359, '668, and '435 patents are in the same family and share the same specification. As an example, the specification of the '069 patent discloses embodiments that contain [redacted]:

> In some embodiments, the cationic lipid may comprise from about 50 mol % to about 90 mol %, from about 50 mol % to about 85 mol %, from about 50 mol % to about 80 mol %, from about 50 mol % to about 75 mol %, from about 50 mol % to about 70 mol %, from about 50 mol % to about 65 mol %, or from about 50 mol % to about 60 mol % of the total lipid present in the particle.

See, e.g., '069 patent at 18:40–46. Because the '069, '359, '668, and '435 patents claim a nucleic acid-lipid particle comprising a [redacted], while the specification discloses [redacted] (emphasis added), Plaintiffs are estopped from enforcing any unclaimed embodiments comprising [redacted]. *Moore U.S.A.*, 229 F.3d at 1107.

Plaintiffs are further legally precluded from claiming that Moderna's [redacted] infringe any Asserted Claims of the '069, '359, '668, and '435 patents under the doctrine of equivalents because to do so would ensnare the prior art (*see, e.g.* the references in Exhibit B of Moderna's Invalidity Contentions). If the claims were to literally cover Moderna's [redacted] then the claims would encompass prior art, including for example US 2008/0020058 A1 at [0887] (Table IV).

Moderna incorporates by reference its Invalidity Contentions to be served according to the scheduling order and any amendments or supplementations thereto concerning the '069, '359, '668, and '435 patents.

3. No Direct or Indirect Infringement of Asserted Claims of the '069 Patent: [redacted]

The Asserted Claims of the '069 patent recite or incorporate a limitation requiring a nucleic acid-lipid particle comprising [redacted] Because the [redacted] do not meet the claim limitation requiring [redacted] do not literally infringe any Asserted Claims of the '069 patent.

There is also no evidence that the [redacted] infringe the referenced claims under the doctrine of equivalents, applying either the function-way-result test, or the insubstantial differences test. If Plaintiffs provide adequate infringement contentions for these claim elements under the doctrine of equivalents, Moderna reserves the right to supplement this response to address those arguments.

In addition, prosecution history estoppel precludes any potential argument by Plaintiffs that Moderna's [redacted] infringe any Asserted Claims of the '069 patent requiring [redacted]

[redacted] under the doctrine of equivalents based on arguments and amendments made during prosecution.

The prosecution history of the '069 patent clearly establishes that the applicants made arguments and amendments, including surrendering claim scope, to overcome the examiner's patentability rejection, which precludes the application of doctrine of equivalents. For example, during the '069 patent prosecution, the applicants deleted "about" from the then-pending claims to narrow the ranges of lipid components in response to the examiner's Section 102 and 103 rejections:

> 1. (Currently amended) A nucleic acid-lipid particle comprising:
> (a) a nucleic acid;
> (b) a cationic lipid comprising from ~~about~~ 50 mol % to ~~about~~ 65 mol % of the total lipid present in the particle;
> (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from ~~about~~ 4 mol % to ~~about~~ 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from ~~about~~ 30 mol % to ~~about~~ 40 mol % of the total lipid present in the particle; and
> (d) a conjugated lipid that inhibits aggregation of particles comprising from ~~about~~ 0.5 mol % to ~~about~~ 2 mol % of the total lipid present in the particle.

'069 patent file history, Amdt. dated August 11, 2011 at 2. Specifically, the applicants stated:

> During the interview, Applicants' representatives proposed amending the claims to delete the word 'about' form the ranges of lipid components and argued that the claimed ranges were not anticipated by McLachlan *et al*. … because that reference failed to disclose the claimed ranges with sufficient specificity ….
>
> * * *
>
> In making both rejections, ***the Examiner alleges that the term 'comprising from about' recited in the instant embraces a broad range of lipid components.*** In an earnest effort to expedite prosecution, but without acquiescing on the merits of the

> rejection, ***Applicants have amended the claims to delete 'about' from the ranges of lipid components recited therein***.

Id. at 6–7 (emphasis added). Therefore, Plaintiffs are precluded from recapturing a nucleic acid-lipid particle comprising [redacted] under doctrine of equivalents, after the applicants relinquished such claim scope and made arguments to overcome prior art during prosecution.

Plaintiffs are further legally precluded from claiming that Moderna's [redacted] infringe any Asserted Claims of the '069 patent under the doctrine of equivalents based on the doctrine of vitiation. The doctrine of equivalents cannot be used to vitiate meaningful limitations from the claims, as the public is entitled to rely on such limitations to avoid infringement. *Johnson & Johnston*, 285 F.3d at 1054. Here, for example, vitiating [redacted] would deprive the public of the notice function of the claims, thus rendering the claims meaningless. *Mirror Worlds*, 692 F.3d at 1358.

Plaintiffs are also legally precluded from claiming that Moderna's [redacted] infringe any Asserted Claims of the '069 patent under the doctrine of equivalents based on the doctrine of public dedication. Plaintiffs are precluded from asserting that any Asserted Claims of the '069 patent cover the [redacted] because the specification of the '069 patent discloses the unclaimed subject matter such that it has been dedicated to the public. *PSC Comput. Prods*, 355 F.3d at 1360. For example, the specification of the '069 patent discloses embodiments that contain [redacted]

> In further preferred embodiments, the non-cationic lipid comprises a mixture of: (i) a phospholipid of from about 10 mol % to about 30 mol % of the total lipid present in the particle . . . . In other embodiments, the non-cationic lipid comprises a mixture of: (i) a phospholipid of from about 10 mol % to about 30 mol %, from about 10 mol % to about 25 mol %, from about 10 mol % to about 20 mol %, from

> about 15 mol % to about 30 mol %, from about 20 mol % to about 30 mol %, from about 15 mol % to about 25 mol %, from about 12 mol % to about 28 mol %, from about 14 mol % to about 26 mol %, or about 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, or 30 mol % (or any fraction thereof or range therein) of the total lipid present in the particle . . . .

'069 patent at 21:15–33; *see also, e.g.*, *id.* at 20:59–21:2, 51:20–29. Because the '069 patent claims [redacted], Plaintiffs are estopped from enforcing any unclaimed embodiments comprising [redacted]. *Moore U.S.A.*, 229 F.3d at 1107.

Plaintiffs are further legally precluded from claiming that Moderna's [redacted] infringe any Asserted Claims of the '069 patent under the doctrine of equivalents because to do so would ensnare the prior art (*see, e.g.* the references in Exhibit B of Moderna's Invalidity Contentions). If the claims were to literally cover Moderna's [redacted], then the claims would encompass prior art, including for example US 2008/0020058 A1 at [0887] (Table IV). Moderna incorporates by reference its Invalidity Contentions to be served according to the scheduling order and any amendments or supplementations thereto concerning the '069 patent.

4. No Direct or Indirect Infringement of Asserted Dependent Claims

The following dependent claims are not infringed, literally or under the doctrine of equivalents:

- Dependent claims directed to [redacted] Moderna incorporates by reference its response to Plaintiffs' Interrogatory No. 7.

- '668 Patent, claims 20–21 and '435 Patent, claims 17–18. [redacted] These claims and the claims that depend from them are not infringed. Moderna incorporates by reference its response to Plaintiffs' Interrogatory No. 7.

- '069 Patent, claim 17; '359 Patent, claim 20; '668 Patent, claim 16; '435 Patent, claim 13; '378 Patent, claims 9, 11, 20, 22, and 27. These dependent claims recite that [redacted] Plaintiffs' April 23, 2023 initial infringement contentions fail to provide details of how Moderna's COVID-19 Vaccine contains [redacted] As a result, Moderna's COVID-19 Vaccine does not infringe any of these asserted dependent claims. [redacted]

- Dependent claims directed to [redacted] are not infringed. For example, '069 Patent, claim 20 is not infringed by [redacted] Moderna's COVID-19 Vaccine, and '359 Patent, claim 19 is not infringed by [redacted] of the Accused Products. Additionally, claim 10 of the '359 Patent is not infringed by [redacted] Moderna's COVID-19 Vaccine, which recites "from 30 mol % to 35 mol % of the total lipid present in the particle." *See supra* Section B.3, which Moderna incorporates by reference as if fully set forth here. Moderna incorporates by reference its response to Plaintiffs' Interrogatory No. 7.

- Dependent claims directed to [redacted] (*e.g.*, '069 Patent, claim 21; '359 Patent, claims 13 and 19; '668 Patent, claim 10) are not infringed by any of Moderna's Accused Products. *See supra* Section B.3, which Moderna incorporates by reference as if fully set forth here. Moderna incorporates by reference its response to Plaintiffs' Interrogatory No. 7.

- Dependent claims directed to [redacted] (*e.g.*, '069 Patent, claim 15; '359 Patent, claim 18; '668 Patent, claim 15; '378 Patent, claim 25) are not infringed by [redacted] Moderna's COVID-19 Vaccine. *See supra* Section B.1, which Moderna incorporates by reference as if fully set forth here. Moderna incorporates by reference its response to Plaintiffs' Interrogatory No. 7.

- Dependent claims directed to [redacted] are not infringed. *See e.g.*, '069 Patent, claim 8 (wherein the cationic lipid comprises from 52 mol % to 62 mol % of the total lipid present in the particle); '359 Patent, claim 7 (50 mol % to 60 mol %). *See supra* Section B.2, which Moderna incorporates by reference as if fully set forth here. Moderna incorporates by reference its response to Plaintiffs' Interrogatory No. 7.

5. No Indirect Infringement of Asserted Patents: No Direct Infringement

Liability under each of §§ 271(b) and (c) requires a finding of direct infringement. *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010) (contributory infringement); *Limelight*

THIRD SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 6 (DEC. 8, 2023):

Moderna incorporates its objections to this Interrogatory as if fully set forth in response to this Interrogatory. Moderna responds as follows:

Pursuant to Fed. R. Civ. P. 33(d), Moderna identifies the following documents from which additional information responsive to the non-objectionable scope of this Interrogatory can be derived or ascertained: MRNA-GEN-00467748, MRNA-GEN-00467749, and MRNA-GEN-00467750.

Moderna's investigation is ongoing and Moderna reserves the right to supplement, revise, or amend Moderna's Response to this Interrogatory as discovery and Moderna's investigation in this Action proceed.

INTERROGATORY NO. 7:

Identify and describe in detail all changes, if any, that were made to any formulation of the Accused Product since the publication of the Moderna/NIH Preprint, which "explained that Moderna's COVID-19 vaccine is composed of mRNA encoding a modified version of the SARS-CoV-2 spike (S) protein that was synthesized, purified, 'and encapsulated into lipid nanoparticles (LNP),' with a lipid molar ratio of '50:10:38.5:1.5 (ionizable lipid:DSPC:cholesterol:PEG-lipid),'"[7] and describe why these changes, including to the lipid molar ratio, if any, were made.

RESPONSE TO INTERROGATORY NO. 7:

Moderna objects to this Interrogatory as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks information about "***all*** changes, if any, that were made to any formulation of the Accused Product since the publication of the Moderna/NIH Preprint," which presumes that all such information is relevant. Moderna will not provide irrelevant and/or non-responsive information relating to aspects of the Accused Products that are

[7] Answer at 37, quoting "SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness," bioRvix.org, at 5–6 (June 11, 2020) ("Moderna/NIH Preprint").

not relevant to the Asserted Claims. Moderna objects to this Interrogatory to the extent it seeks information protected from discovery by the attorney-client privilege, attorney work product doctrine, or any other applicable privilege or immunity, and Moderna will not provide or produce such information. Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, specifically because it lacks reasonable geographic restrictions. Moderna will not provide information relating to doses that were not made, used, offered for sale, or sold within the United States or imported into the United States, which are not accused of infringement. Moderna objects to this Interrogatory as premature to the extent that it calls for the rendering of an expert opinion. Moderna objects to this Interrogatory to the extent it seeks information relating solely to batches and doses of the Accused Products subject to safe harbor under 35 U.S.C. § 271(e)(1), which are not proportional to the needs of the case. Moderna will not provide or produce such information.

Subject to the General and Specific Objections, Moderna responds as follows:

[redacted]

[redacted]

Pursuant to Fed. R. Civ. P. 33(d), Moderna identifies the above documents from which information responsive to the non-objectionable scope of this Interrogatory can be derived.

Moderna's investigation is ongoing and Moderna reserves the right to supplement, revise, or amend Moderna's Response to this Interrogatory as discovery and Moderna's investigation in this Action proceed.

INTERROGATORY NO. 8:

Identify and describe in detail all license agreements, and proposed license agreements, whether or not ultimately executed, related to the Accused Product or the Patents-in-Suit or any agreements, whether or not ultimately executed, that you contend are relevant to the determination of damages in this action, including, but not limited to, license agreements, covenants, releases, and settlements, and provide all of your bases for why you contend each agreement relates to the Accused Product or the Patents-in-Suit or why it is relevant to the determination of damages in this action.

RESPONSE TO INTERROGATORY NO. 8:

Moderna objects to this Interrogatory as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, specifically because it seeks information about "all license agreements, and proposed license agreements, whether or not ultimately executed" relating to subject matter and "license agreements, covenants, releases, and settlements," which seeks information regarding activities outside the United States, and to the extent it seeks information related to products not at issue in this action. Moderna further objects to this Interrogatory as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks information

about "proposed license agreements," which presumes that all such information is relevant. Moderna also objects to this Interrogatory as unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case to the extent it covers non-patent license agreements. Moderna objects to this Interrogatory as premature to the extent that it calls for the rendering of an expert opinion, specifically because it asks for identification of agreements "relevant to the determination of damages in this action" "provid[ing] all of your bases for why you contend each agreement relates to the Accused Product or the Patents-in-Suit or why it is relevant to the determination of damages in this action." Moderna objects to this Interrogatory to the extent it seeks to improperly shift the burden of proving the entitlement of damages from Plaintiffs to Moderna. Moderna objects to this Interrogatory to the extent it seeks information or the identification of documents and things subject to confidentiality obligations owed to third parties (by agreement or by law) that prohibit or restrict their disclosure by Moderna. Moderna may identify documents in response to this Interrogatory that include redactions made or maintained at the direction of U.S. Government. Modern further objects to this Interrogatory for being unlimited in time or not limited to a time frame relevant to this litigation, and therefore unduly burdensome, overly broad, and not proportional to the needs of the case. Moderna objects to this Interrogatory to the extent it seeks information protected from discovery by the attorney-client privilege, attorney work product doctrine, or any other applicable privilege or immunity, and Moderna will not provide or produce such information.

Subject to the General and Specific Objections, Moderna responds as follows:

[redacted]

[redacted] Pursuant to Fed. R. Civ. P. 33(d), Defendants will produce executed versions of the aforementioned agreements and other non-privileged documents, including documents on which it intends to rely to support its response any damages contentions by Plaintiffs, from which information responsive to the non-objectionable scope of this Interrogatory can be derived.

Moderna further identifies Said Francis as knowledgeable about the aforementioned executed patent license agreements.

Moderna's investigation is ongoing and Moderna reserves the right to supplement, revise, or amend Moderna's Response to this Interrogatory as discovery and Moderna's investigation in this Action proceed.

FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 8 (JUNE 12, 2023):

Moderna incorporates its objections to this Interrogatory as if fully set forth in response to this Interrogatory. Moderna responds as follows:

Pursuant to Fed. R. Civ. P. 33(d), Moderna identifies the following documents from which additional information responsive to the non-objectionable scope of this Interrogatory can be derived or ascertained: MRNA-GEN-00225516 – MRNA-GEN-00226020.

Moderna's investigation is ongoing and Moderna reserves the right to supplement, revise, or amend Moderna's Response to this Interrogatory as discovery and Moderna's investigation in this Action proceed.

INTERROGATORY NO. 9:

To the extent that you contend that there exist commercially acceptable and available non-infringing alternatives with respect to the Accused Product and the Patents-in-Suit, identify with particularity such non-infringing alternatives, how each non-infringing alternative differs from the Accused Product and why you believe it is non-infringing, why you believe it would have been commercially acceptable, the dates on which such alternatives were available, the cost of

implementation for each, the effect of implementation for each, including any studies, tests, or analyses of these costs and effects, and any documents on which you intend to rely in connection with each non-infringing alternative.

RESPONSE TO INTERROGATORY NO. 9:

Moderna objects to this Interrogatory as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, specifically because it seeks "any studies, tests, or analyses" relating to subject matter and because this Interrogatory seeks information regarding activities outside the United States, and because it seeks information related to products not at issue in this action. Moderna objects to this Interrogatory as premature and unanswerable at this time because Plaintiffs have not identified Asserted Claims of the Patents-in-Suit, nor served infringement contentions identifying each Accused Product, and Plaintiffs bear the burden of proving infringement. Moderna objects to this Interrogatory as unduly burdensome because Moderna's ability to respond has been prejudiced by Plaintiffs' failure to respond to Moderna's Interrogatory No. 5 concerning the bases for Plaintiffs' claim for damages. Moderna objects to this Interrogatory on the ground that it seeks premature discovery in advance of the dates to be set out by the Court or agreed to by the parties because it seeks to elicit a claim construction position. Moderna objects to this Interrogatory as vague and ambiguous as to the terms "commercially acceptable," "available," "the cost of implementation," "the effect of implementation," none of which are defined. Moderna objects to this Interrogatory to the extent it seeks information that is not known or reasonably available to Moderna, or that is not within Moderna's possession, custody, or control, specifically as to seeking "the cost of implementation," "the effect of implementation," and "any studies, tests, or analyses of these costs and effects" for products of any third parties. Moderna objects to this Interrogatory as consisting of multiple discrete subparts that separately count towards Plaintiffs' total permissible number of interrogatories under Fed. R. Civ. P. 33. Plaintiffs' request for an

identification "with particularity of such non-infringing alternatives" counts as at least five subparts. Moderna objects to this Interrogatory to the extent it seeks information protected from discovery by the attorney-client privilege, attorney work product doctrine, or any other applicable privilege or immunity, and Moderna will not provide or produce such information. Moderna objects to this Interrogatory as premature to the extent that it calls for the rendering of an expert opinion.

Subject to the General and Specific Objections, Moderna responds as follows:

Moderna objects to this Interrogatory as premature and unanswerable at this time because Plaintiffs have not yet served Infringement Contentions or identified Asserted Claims of the Patents-in-Suit. Nevertheless, Moderna identifies Moderna's COVID-19 Vaccine as a non-infringing alternative.

In addition to producing documents on which Moderna intends to rely, Moderna may rely on testimony and opinions from Moderna's expert(s) to be disclosed in accordance with the scheduling order.

Moderna's investigation is ongoing and Moderna reserves the right to supplement, revise, or amend Moderna's Response to this Interrogatory as discovery and Moderna's investigation in this Action proceed.

INTERROGATORY NO. 10:

For any Accused Product, describe in detail your contention about the relevant market and competitive substitutes for the Accused Product or the inventions in the Patents-in-Suit, your contention about the date of any hypothetical negotiation for each of the Patents-in-Suit, your contention about the basis for any consumer demand for the Patents-in-Suit, your contention about the appropriate reasonable royalty rate and base including your contention on whether or not there is an established royalty, and the complete factual and legal bases for all of the foregoing. As part of your response, identify all documents that you contend support your response.

RESPONSE TO INTERROGATORY NO. 10:

Moderna objects to this Interrogatory as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, specifically because it seeks "all documents" supporting Moderna's response to this Interrogatory. Moderna objects to this Interrogatory as vague and ambiguous at least as to the term "competitive substitutes," which is not defined. Moderna objects to this Interrogatory as unduly burdensome because Moderna's ability to respond has been prejudiced by Plaintiffs' failure to respond to Moderna's Interrogatory No. 5 concerning the bases for Plaintiffs' claim for damages. Moderna objects to this Interrogatory as premature and unanswerable at this time because Plaintiffs have not identified Asserted Claims of the Patents-in-Suit nor identified each Accused Product, and Plaintiffs bear the burden of proving infringement. Moderna objects to this Interrogatory as consisting of multiple discrete subparts that separately count towards Plaintiffs' total permissible number of interrogatories under Fed. R. Civ. P. 33. Plaintiffs' request for complete legal and factual bases five separate "contentions" counts as at least five subparts. Moderna objects to this Interrogatory to the extent it seeks information protected from discovery by the attorney-client privilege, attorney work product doctrine, or any other applicable privilege or immunity, and Moderna will not provide or produce such information. Moderna objects to this Interrogatory as premature to the extent that it calls for the rendering of an expert opinion.

Subject to the General and Specific Objections, Moderna responds as follows:

Pursuant to Fed. R. Civ. P. 33(d), Defendants will produce non-privileged documents from which additional information responsive to the non-objectionable scope of this Interrogatory can be derived.

In addition to producing documents on which Moderna intends to rely, Moderna may rely on testimony and opinions from Moderna's expert(s) to be disclosed in accordance with the scheduling order.

Moderna's investigation is ongoing and Moderna reserves the right to supplement, revise, or amend Moderna's Response to this Interrogatory as discovery and Moderna's investigation in this Action proceed.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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